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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/588,725	08/08/2006	Hashime Kanazawa	2006_1265A	1971

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WENDEROTH, LIND & PONACK, L.L.P.
1030 15th Street, N.W.,
Suite 400 East
Washington, DC 20005-1503

EXAMINER	
LAU, JONATHAN S	
ART UNIT	PAPER NUMBER
1623	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/588,725	KANAZAWA ET AL.	
	Examiner	Art Unit	
	Jonathan S. Lau	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 Jun 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,10-13 and 15-21* is/are pending in the application.

4a) Of the above claim(s) *18* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,10-13,15-17 and 19-21* is/are rejected.

7)☒ Claim(s) *15* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01 Jun 2009 has been entered.

This Office Action is responsive to Applicant's Amendment and Remarks, filed 01 Jun 2009, in which claims 1, 16 and 17 are amended to change the scope and breadth of the claim, claims 2-9, 14 and 22 are canceled, and claims 10 and 19-21 are amended to change dependency.

This application is the national stage entry of PCT/JP05/01801, filed 08 Feb 2005; and claims benefit of foreign priority document JAPAN 2004-032329, filed 09 Feb 2004.

Claims 1, 10-13, 15-21 are pending in the current application. Claim 18, drawn to a non-elected invention, is withdrawn.

Rejections Withdrawn

Applicant's Amendment, filed 01 Jun 2009, with respect to claims 1-3, 6-17 and 19-22 rejected under 35 U.S.C. 103(a) as being unpatentable over Bussolari et al. (US Patent Application Publication US 2003/0045553, published 6 Mar 2003, cited in PTO-892) has been fully considered and is persuasive, as claims 2-9, 14 and 22 are canceled and Bussolari et al. does not specifically teach the proportion of the α-glucosidase inhibitor voglibose is 0.01 to 10 parts by weight relative to 100 parts by weight of fenofibrate required by amended claims 1, 16 and 17 and Applicant's remarks regarding the teaching of Bussolari et al. are persuasive in view of the claims as amended.

This rejection has been **withdrawn**.

Applicant's Amendment, filed 01 Jun 2009, with respect to claims 12, 14, 20 and 22 rejected under 35 U.S.C. 112, second paragraph, as being indefinite has been fully considered and is persuasive, as claims 12, 14, 20 and 22 do not recite the phrases "an agent for the treatment of at least one symptom selected from the group consisting of hyperlipemia, a symptom of diabetes, diabetes complications, a symptom of hyperglycemia after a meal in diabetics, impaired glucose tolerance (IGT), decrease of glucose tolerance, a symptom of hypertension, hyperinsulinemia, hyperammonemia, obesity or a complication thereof, fatty liver, and a symptom of hepatitis" or "an agent for the treatment of at least one symptom selected from the group consisting of a symptom of diabetes, diabetes complications and a symptom of hyperglycemia after a meal in diabetics."

This rejection has been **withdrawn**.

Claim Objections

Claim 15 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 15 depends from claim 1 and substantially recites the limitations of lines 8-12. While claim 15 at line 2 recites a pharmaceutical "preparation" instead of a "composition", these terms are synonymous. Therefore amended claim 15 does not appear to further limit the subject matter of claim 1.

Applicant is advised that should claims 11-13 be found allowable, claims 19-21 will be objected to under 37 CFR 1.75 as being a substantial duplicate thereof. When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Amended claims 19-21 now depend from claim 1 and are therefore substantial duplicates of claims 11-13 respectively.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Amended Claims 1, 11-13, 15-17 and 19-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claims 1, 16 and 17 recite "fenofibrate or a salt thereof" and "voglibose or a salt thereof."

The specification discloses salts, such as pharmaceutically acceptable salts at page 14, lines 10-15 which meet the written description and enablement provisions of 35 USC 112, first paragraph. However, claims 1, 11-13, 15-17 and 19-21 are directed to encompass all salts, which only correspond in some undefined way to specifically instantly disclosed chemicals. None of these salts meet the written description requirement of 35 USC 112, first paragraph, due to lacking chemical structural information for what they are and because chemical salts are highly variant and encompass a myriad of possibilities. The specification provides insufficient written description to support the genus encompassed by the claim. For example, the '201 PGPub (US Patent Application Publication 2002/0147201, published 10 Oct 2002, cited in PTO-892) discloses active agents made into salts with glycyrrhizin for administration to a subject (abstract). Glycyrrhizin is well-known to possess anti-viral and hepatoprotective activity. The specification does not reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession

of the claimed invention such as the salt of glycyrrhizin taught by the '201 PGPub having a distinct pharmacological activity, or the entire genus of possible salts having any possible pharmacological activity. As noted above, the specification reasonably conveys to one skilled in the relevant art that the genus of "pharmaceutically acceptable salts" is described, because the understanding within the art is that nature of the biological response to a "pharmaceutically acceptable salt" of a compound is no different to the nature of the response to the parent compound, though the intensity may differ.

Vas-Cath, Inc. v. Mahurkar, 935 F.2d 935 F.2d 1555, 1563 [19 USPQ2d 1111] (Fed. Cir. 1991), makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession *of the invention*. The invention is, for purposes of the 'written description' inquiry, *whatever is now claimed*." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (*Vas-Cath* at page 1116.)

Therefore, only the structurally defined chemical compounds, but not the full breadth of the claims, meet the written description requirement of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus of all salts is highly variant and encompasses salts having a distinct pharmacological activity in addition to the base active agent such as fenofibrate or voglibose. However, as noted above, the specification reasonably conveys to one

skilled in the relevant art that the genus of "pharmaceutically acceptable salts" is described.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Amended Claims 1, 10-13, 15-17 and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chen et al. (US Patent 6,982,281, filed 17 Nov 2000, cited in PTO-892) in view of Keating et al. (Drugs, 2002, 16(13), p1909-1944, cited in PTO-892) and Goke et al. (Digestion, 1995, 56, p493-501, cited in PTO-892).

Chen et al. teaches a pharmaceutical compositions and dosage forms comprising fenofibrate (abstract). Chen et al. teaches the compositions and dosage

forms comprising an additional active agent, with a preferred embodiment wherein said additional active agent is contained within the compositions and dosage forms, and that the weight ratio will depend upon the effective dose of each ingredient (column 8, lines 5-15). Chen et al. teaches examples of said additional active agent include α-glucosidase inhibitors (column 8, lines 40-45) and teaches the particularly preferred α-glucosidase inhibitor is voglibose (column 9, lines 20-25). Chen et al. teaches the composition is prepared by conventional methods well known to those skilled in the art such as mixing (column 13, lines 25-30). Chen et al. teaches it is within the level of skill in the art to optimize the amount or percentage of active agent present in the composition and dosage form based on the need of the patient and can be determined by the attending clinician (column 12, lines 25-35).

Chen et al. does not specifically teach the proportion of the α-glucosidase inhibitor voglibose is 0.01 to 10 parts by weight relative to 100 parts by weight of fenofibrate (instant claims 1, 16 and 17).

Keating et al. teaches the effect dosage of fenofibrate is 160 mg or 200 mg as monotherapy or combination therapy (page 1910, paragraph 2-3).

Goke et al. teaches the effective dosage of voglibose is 0.5, 1.0, 2.0, or 5.0 mg three times daily (abstract).

It would have been obvious to one of ordinary skill in the art to combine Chen et al. in view of Goke et al. and Keating et al. One of ordinary skill in the art would be motivated to combine Chen et al. in view of Goke et al. and Keating et al. because Chen et al. teaches the weight ratio of the active agents will depend upon the effective dose of

each ingredient, and Keating et al. and Goke et al. teach the effective dose of the respective active agents. One of ordinary skill in the art would have a reasonable expectation of success in combining Chen et al. in view of Goke et al. and Keating et al. because Chen et al. teaches it is within the level of skill in the art to optimize the amount or percentage of active agent present in the composition and dosage form. The composition taught by Chen et al. meets all structural limitations of the intended use of "reducing a side effect or dose of an α-glucosidase inhibitor" because Chen et al. teaches the dose can be reduced based on the need of the patient and can be determined by the attending clinician and it is well-known in the art that side effects will be dose-dependent and will be reduced with a reduced dose. Claims 11-13 and 19-21 are interpreted as the intended use of a pharmaceutical composition, and the composition taught Chen et al. in view of Goke et al. and Keating et al. renders obvious all structural limitations required by the intended use and therefore is capable of meeting the intended use.

Response to Applicant's Remarks:

Applicant's Remarks, filed 01 Jun 2009, have been fully considered and found not to be persuasive.

Applicant's remarks showing the non-additive effect of voglibose and fenofibrate have been carefully considered and found not to be commensurate in scope with the claims. As noted by Applicant, the magnitude of the non-additive combined effect is significant when compared to the magnitude of the effect of each agent individually. However, this non-additive property is drawn to the combined administration of the two

agents (instant specification page 35). The invention as claimed does not require structural limitations of the composition, such as wherein both agents are formulated as a single dosage form, commensurate in scope with this non-additive property drawn to the combined administration of the two agents. The invention as claimed encompasses the composition comprising two agents, including as separate components, which can be used for separate administration (instant specification, page 16-17). Similarly, while claim 16 recites "mixing" the agents, the ordinary definition of "mix" includes "to combine with another", encompassing combining separate components (entry 1a(2) for definition of mix, Merriam-Webster Online Dictionary, cited in PTO-892). Therefore the showing of the non-additive effect of voglibose and fenofibrate in combined administration is not persuasive because it is not commensurate in scope with the invention as claimed. This showing of a non-additive effect drawn to the combined administration of the two agents is persuasive for compositions having structural limitations requiring combined administration.

Conclusion

No claim is found to be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jonathan S. Lau whose telephone number is 571-270-3531. The examiner can normally be reached on Monday - Thursday, 9 am - 4 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Anna Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jonathan Lau
Patent Examiner
Art Unit 1623

/Shaojia Anna Jiang/
Supervisory Patent Examiner
Art Unit 1623